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Exploration of preterm birth rates associated with different models of antenatal midwifery care in Scotland: Unmatched retrospective cohort analysis

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**Exploration of preterm birth rates associated with different models of antenatal  
midwifery care in Scotland: unmatched retrospective cohort analysis**

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*Abstract*

**Objectives.** Preterm birth represents a significant personal, clinical, organisational and financial burden. Strategies to reduce the preterm birth rate have had limited success. Limited evidence indicates that certain antenatal care models may offer some protection, although the causal mechanism is not understood. We sought to compare preterm birth rates for mixed-risk pregnant women accessing antenatal care organised at a freestanding midwifery unit (FMU) and mixed-risk pregnant women attending an obstetric unit (OU) with related community-based antenatal care.

**Methods.** Unmatched retrospective 4-year Scottish cohort analysis (2008-2011) of mixed-risk pregnant women accessing i) FMU antenatal care (n=1,107); ii) combined community-based and OU antenatal care (n=7,567). Data were accessed via the Information and Statistics Division of the NHS in Scotland. Aggregates analysis and binary logistic regression were used to compare the cohorts' rates of preterm birth; and of spontaneous labour onset, use of pharmacological analgesia, unassisted vertex birth, and low birth weight. Odds ratios were adjusted for age, parity, deprivation score and smoking status in pregnancy.

**Findings.** After adjustment the 'mixed risk' FMU cohort had a statistically significantly reduced risk of preterm birth (5.1% [n=57] vs. 7.7% [n=583]; AOR 0.73 [95% CI 0.55-0.98]; p=.034). Differences in these secondary outcome measures were also statistically significant: spontaneous labour onset (FMU 83.9% vs OU 74.6%; AOR 1.74 [95% CI 1.46-2.08]; p<0.001); minimal intrapartum analgesia (FMU 53.7% vs OU 34.4%; AOR 2.17 [95% CI 1.90-2.49]; p<0.001); spontaneous vertex delivery (FMU 71.9% vs OU 63.5%; AOR 1.46 [95% CI 1.32-1.78]; p<0.001). Incidence of low birth weight was not statistically significant after adjustment for other variables. There was no significant difference in the rate of perinatal or neonatal death.

Conclusions. Given this study's methodological limitations, we can only claim associations between the care model and or chosen outcomes. Although both cohorts were mixed risk, differences in risk levels could have contributed to these findings. Nevertheless, the significant difference in preterm birth rates in this study resonates with other research, including the recent Cochrane review of midwife-led continuity models. Because of the multiplicity of risk factors for preterm birth we need to explore the salient features of the FMU model which may be contributing to this apparent protective effect. Because a randomised controlled trial would necessarily restrict choice to pregnant women, we feel that this option is problematic in exploring this further. We therefore plan to conduct a prospective matched cohort analysis together with a survey of unit practices and experiences.

Keywords.

Pregnancy; model of antenatal care; midwifery; midwife-led care; preterm birth.

*Introduction*

Preterm birth is rising in almost all countries with reliable data (WHO 2012). Preterm babies are disproportionately represented in mortality and morbidity figures. In addition to the personal distress involved – which includes potential long-term health deficits for the child - this clinical feature involves significant financial and organisational resources (Petrou 2005; Mangham et al 2009). Lisonkova et al (2011) note the importance of the iatrogenic element which was held to have increased preterm birth rates in the USA. Although the US rate has fallen slightly in recent years (from a peak of 12.8% in 2006 to 11.7% in 2011; March of Dimes 2012) - it is still a critical concern. Associated US medical and educational expenditure was estimated in 2005 to exceed \$26 billion. While the UK preterm birth rate is significantly lower (7.6% in 2010; WHO 2012), it is still a matter of grave concern, not least for the financial implications: Mangham et al (2009) estimate that the public sector cost in England and Wales in 2006 was £2.95 billion (US\$4.57 bn).

It is acknowledged that preterm birth has a complex epidemiology (Goldenberg et al 2008), but despite extensive research (Steer 2005; Goldenberg et al 2008) its incidence has not been reduced (Steer 2006). Nevertheless, growing evidence suggests that the model of antenatal care may have an effect on the likelihood of spontaneous preterm birth. A recently revised Cochrane review found significantly reduced preterm birth rates for ‘continuity models’ of midwifery care (Sandall et al 2013), although most of the included studies were for ‘low-risk’ women. The two studies which reflected a mixed-risk caseload showed a non-statistically significant reduction; only one of the seven included trials included community-based care.

Allen et al’s (2012) review of alternative maternity care provision found that ‘non-standard’ models were associated with a reduced incidence of preterm birth, as well as more frequent antenatal visit attendance and increased breastfeeding initiation. Allen et al (2012) defined ‘standard’ care as that provided by rostered hospital staff, whereas ‘non-standard’ care

included midwifery group practices, group antenatal care, and Young Women's Clinics. Their review included a discussion of the Centering Pregnancy™ Group Antenatal Care scheme (Klima et al 2009; Dellos and Marshall 2011). Results from such schemes suggest that outcomes are significantly improved even in groups which usually have poorer than average outcomes (such as teenage mothers and those from deprived backgrounds), although to date the scheme has not been the subject of a randomised controlled trial within the UK. A non-statistically significant difference in preterm birth rates (4% vs. 6%) was found in Tracy et al's (2013) comparison of 'caseload' and 'standard' midwifery care. A finding of a highly significant difference in preterm birth rates was also found in a matched cohort study comparing clinical outcomes for women receiving 'standard' National Health Service (NHS) care and women employing an independent midwife (Symon et al 2009); 87% of the latter were planning a homebirth [66% achieved this]. In that study results were adjusted for several risk factors including medical and previous obstetric complications, so off-setting one of the criticisms levelled at evaluations of 'non-standard' antenatal care packages – that they focus principally on birth outcomes for 'low-risk' women (*cf.* Reddy et al 2004). However, Hollowell et al's (2011) systematic review found that there was insufficient evidence of different antenatal care programmes reducing infant mortality (and preterm birth, a major factor in such mortality) in disadvantaged or vulnerable groups, and they concluded that the quality of evidence overall was poor.

Re-shaping midwifery care in an attempt to reduce preterm birth is an emerging theme (McNeil and Reiger 2014) and offers significant potential savings (Skelton et al 2009). However, the low numbers in the UK accessing the independent midwifery and Centering Pregnancy™ models make evaluations of such schemes problematic; and the fact that many midwife-led units (MLUs) focus largely on 'low-risk' women is a limiting factor. Much of the literature concerning MLUs does not distinguish between different types of unit, treating

freestanding and alongside units as a single entity (Stewart et al 2005). If only 'low-risk' women are included in most MLU studies this restricts comparisons with other models which cater for women of all risk levels. A potential solution is to explore the mixed-risk freestanding midwifery unit (FMU) model because women of any risk status may receive at least some of their antenatal care there.

#### *'Freestanding' midwifery units (FMU)*

While there is no single FMU model, over 23,000 women a year give birth in a FMU in England (TIC 2006); in Scotland over 1,200 women gave birth in a FMU in 2010 (BirthChoice UK 2010). In addition, many FMUs offer antenatal care to women with a range of risk levels within a defined locality, irrespective of planned place of birth. This broader risk profile offers up the possibility of comparing results with 'standard' antenatal care models which cover women of all risk levels.

Most FMUs, known in some places as 'stand-alone units', are "situated away from a main obstetric hospital, often in a small community hospital" (BirthChoice UK, nd). Women with defined medical conditions or obstetric risk factors will receive most antenatal care on a 'shared' basis in the obstetric unit, and may be booked to give birth there, but in some cases are also free to access local FMU care. This focus on providing care away from centralised hospitals reflects government priorities throughout the UK (DH 2004; MSAG 2011; Welsh Government 2011; DHSSPS 2013). This is particularly the case in Scotland, where many of those in remote and rural areas (such as the Highlands and Islands) do not have immediate access to obstetric unit (OU) services. BirthChoice UK lists 35 maternity units in Scotland, of which 20 are designated 'small' (range 6-330 births per year; average <100).

Many women receiving FMU care will plan to have their baby in that unit; some will be transferred to an OU because of pregnancy or intrapartum complications. Transfer rates vary



by type of unit ('freestanding' or 'alongside') and parity (NICE 2007), but in most if not all such cases the woman will have received the antenatal care package originating in the FMU. While reviews of FMUs focus largely on intrapartum care (Newburn and Singh 2003; Overgaard et al 2011), it is the antenatal care package with which we are interested here because our principal focus is on the risk of preterm birth. We emphasise that this study was concerned with the locus of antenatal care, not with planned or actual place of birth.

### *The study*

Within our locality is a FMU which offers antenatal care to women of all risk levels, irrespective of planned place of birth. Uptake of this antenatal care package is extremely high, with very few women opting for exclusive care at the associated obstetric unit thirty miles away. Those women who require obstetric input or review (for example because of pre-eclampsia or previous caesarean section) can receive this on-site when a consultant obstetrician visits on a periodic basis (usually fortnightly). Specialist services, for example for insulin-dependent diabetics, are accessed at the associated OU, but in almost all cases these women also attend the FMU for midwife-led antenatal care. The presence of defined risk criteria does not preclude access to antenatal care there, and indeed only in exceptional cases do pregnant women receive all their care at the OU.

The FMU claims to promote a calm environment dedicated to woman/family-centred care, a flexible 'drop-in' service, and encouraging the woman to be an active participant (Winters and Nicoll 2006). Because all women living in this locality are eligible for at least some antenatal care at the FMU (and indeed uptake is known to be very high), we hypothesised that they would have a lower incidence of preterm birth compared with women receiving 'standard' antenatal care in the city where the associated OU is sited. Women living within

the FMU locality were placed in the FMU cohort irrespective of any risk factors because of the likelihood that they would encounter the antenatal care model there for at least some of the time, although we cannot say for sure what a ‘dose response’ might be. For the years in question, ‘standard’ OU care consisted of a mixture of community-based and OU-based antenatal care, reflecting the original Scottish maternity care policy recommendations (Scottish Executive 2001). We also hypothesised that onset of labour, use of pharmacological analgesia, type of birth, and incidence of low birth weight may be improved in the FMU cohort, whether they gave birth in the FMU or in the OU.

There is an inherent geographical selection bias in this study, but across most of Scotland this reflects reality: women tend to receive the care package implemented in their local area. In part this indicates the absence of the ‘purchaser-provider’ aspect of health care as experienced elsewhere in the UK (Timmins 2013). Except for certain specialist services there is not a tradition in Scotland of patients accessing non-local services. We took advantage of this geographical bias because each locality had women of mixed risk levels. ‘Mixed risk’ is taken to mean a combination of ‘low risk’ and ‘higher risk’ - the current categories used to denote risk status in the Scottish Woman-Held Maternity Record [SWHMR] (HIS 2009).

### *Methods*

This was a retrospective observational study to compare preterm birth rates between two cohorts. Data acquisition and analysis were by the local Epidemiology and Biostatistics Unit (‘the Epidemiology unit’), which has access to birth data through the Information and Statistics Division (ISD) of the NHS in Scotland. From this birth record database, taken from the national maternity dataset which a Data Quality Assurance Report described as “very robust” (ISD 2010: 2), postcodes were used to identify women who had given birth between 2008 and 2011 and who had either accessed the FMU care package or who had received the

care package offered within the city where the OU is sited (since 2009 with an ‘alongside’ MLU). The allocation to FMU or OU group was based on the woman’s postcode. Local practitioners confirmed that almost all women living near the FMU do access care there, irrespective of their risk level; and women living near the OU do not travel the thirty miles to the FMU to receive antenatal care. We were not able to match by or adjust for individual risk factors.

Our database contained the following data items: a unique hospital number from which the mother’s age was calculated; postcode (ZIP code); gestation at birth; onset of labour (spontaneous / induced); use of intrapartum analgesia; date of baby’s birth; type of birth; baby’s birth weight, smoking status at booking and during pregnancy. Once the Epidemiology unit had calculated the mother’s age and deprivation quintile from her unique hospital number and postcode, the latter fields were deleted from the database; the Epidemiology unit held the postcode separately for verification checks. Deprivation levels were taken into account because of known differences in the socio-demographic composition of the OU and FMU cohorts. These were calculated using quintiles of the Scottish Index of Multiple Deprivation (SIMD) - the Scottish Government’s official tool for assessing deprivation – where SIMD1 is the most deprived, and SIMD5 is the least deprived.

Simple aggregates outcomes for the FMU and OU cohorts were compared for the incidence of preterm births, and for the following secondary outcome measures: i) spontaneous onset of labour, ii) use of pharmacological analgesia, iii) unassisted vertex birth, and iv) low birth weight. Univariate comparisons between the FMU and OU cohorts were performed using the chi-square test for nominal variables, the chi-square test for trend for ordinal variables and t-tests for interval variables. Binary logistic regression was used to identify the effects of the independent variables (mother’s age in years, parity, smoking status during pregnancy and deprivation level [SIMD quintile]) on the odds of preterm birth, and the odds for the

following secondary outcome measures: onset of labour; birth other than spontaneous; birth weight <2500g; need for pharmacological analgesia. Independent variables with  $p < 0.300$  in univariate analyses were included in multivariate analyses. Analysis was carried out using SPSS version 21.

We obtained confirmation that formal ethics committee approval was not required for this study as it contained only anonymous data (Ref: CYA/AG/12/GA/046). Full R&D and Caldicott Guardian permissions were obtained.

## Findings

The FMU and OU cohorts comprised 1,107 and 7,567 mothers respectively. Deprivation level varied widely, as indicated in Table 1: mothers in the FMU cohort were much less likely to be from SIMD1, the most deprived quintile ( $\chi^2_{\text{trend}}=151.79$ ,  $df=1$ ,  $p<0.001$ ). On average FMU cohort mothers were also slightly older (although only by seven months on average) and were significantly less likely to be primiparous. However, they were more likely to be smokers at booking (FMU 30.8%; OU 25.7%;  $\chi^2=17.30$ ,  $df=1$ ,  $p<0.001$ ), and to have smoked during pregnancy.

**Table 1** *Comparison of socio-demographic characteristics and parity, OU and FMU care model cohorts*

The babies of FMU cohort mothers were slightly heavier. While this difference was statistically significant ( $t=6.48$ ,  $df=316$ ,  $p<0.001$ ), it averaged just 64g in birth weight. Despite the mean gestation in each group being similar (FMU 39.40 weeks; OU 39.18 weeks) the difference was statistically significant ( $t=3.22$ ,  $df=8672$ ,  $p=0.001$ ). There was also a significant difference when the cohorts were compared by gestational group ( $\chi^2_{\text{trend}}=7.69$ ,  $df=1$ ,  $p=0.006$ ) (Table 2).

**Table 2** *Comparison of gestation and birth weight, OU and FMU care model cohorts*

Place of birth varied, with almost half the FMU cohort giving birth in the OU (Table 3). A small number gave birth in an adjacent NHS Health Board's obstetric unit.

**Table 3** *Place of birth by antenatal care model*

Table 4 shows the comparison of rates for the primary and secondary outcome measures.

**Table 4** *Comparison of outcome measures for different antenatal care models: FMU vs. OU cohorts*

The preterm birth rate was 5.1% in the FMU cohort compared with 7.7% in the OU cohort. After adjusting for SIMD quintile, age, parity and smoking status during pregnancy, the odds ratio for preterm birth was statistically significant (FMU:OU AOR 0.73 [0.55-0.98],  $p=0.034$ ). The overall effect of SIMD was not significant at the 5% level ( $p=0.088$ ) but there is some evidence to suggest this factor is involved: the odds for two quintiles were raised compared with SIMD1 [the most deprived quintile] (SIMD3 AOR 1.39 [1.03-1.89],  $p=0.033$ ; SIMD4 AOR 1.33 [1.02-1.75],  $p=0.037$ ).

Women in the FMU cohort were also more likely to have a spontaneous labour onset (AOR 1.74 [1.46-2.08],  $p<0.001$ ), minimal intrapartum analgesia (AOR 2.17 [1.90-2.49],  $p<0.001$ ), and to have babies born by spontaneous vertex delivery (AOR 1.46 [1.32-1.78],  $p<0.001$ ). All odds ratios were adjusted for the confounding variables. The incidence of low birth weight was not statistically significant once adjusted for other factors. There was also a non-statistically significant difference in the rate of perinatal / neonatal death.

## Discussion

In this unmatched ‘mixed risk’ cohort study which compared two antenatal care models we found a significantly lower preterm birth rate for women accessing the FMU model of care. We emphasise that we are not comparing the cohorts by place of birth but by antenatal care package. Women with defined antenatal risk factors were still eligible for at least some care at the FMU, and uptake of this amongst ‘higher risk’ women is very high. Our findings reflect other studies and reviews of ‘non-standard’ antenatal care (Symon et al 2009; Allen et al 2012; Sandall et al 2013). While observational studies are low in the hierarchy of research evidence, our findings do appear to be a further indicator that there may be something in the antenatal care model which affects the likelihood of preterm birth.

The women in the FMU cohort also had statistically significantly better outcomes in terms of spontaneous labour, intrapartum analgesia, normal birth and low birth weight, although we concede that statistical and clinical significance are not synonymous. There are many possible confounding factors for these outcomes, including place of birth and selection bias; at present we can only report an association between these variables. In addition, the pattern of maternity care provision in the UK is complex - the lack of standardisation, even between units which share the same designation, makes drawing lessons difficult. However, it may be that a sensitive FMU model of care can lead to significant clinical benefits. Walsh and Devane (2012) suggest that greater ‘agency’ enjoyed by women and smallness of scale may help MLUs achieve better outcomes.

Our study had the advantage of being able to compare women of varying risk levels who received different models of antenatal care, so minimising one possible source of bias. In common with the latest Cochrane review we have used the term ‘mixed risk’; other papers have used the term ‘all risk’ and ‘any risk’ to denote the same idea of a population not being restricted to a notional ‘low-risk’ or ‘high-risk’ designation (Tracy et al 2013). In practice,

higher risk women in the FMU catchment area accessed FMU care as well as travelling to the OU for obstetric or other specialist services. However, we did not assess 'risk status' in these cohorts, and acknowledge that different degrees of risk may account for some of the differences we found. That said, the lack of a widely-accepted and sensitive risk scoring tool for pregnant women is an issue. In an attempt to be comprehensive, antenatal risk screening has become very broad, although the very act of labelling a woman 'not low-risk' may in fact predispose her to poorer outcomes (Alexander and Keirse 1989). Given that a recent national evaluation in Scotland found that 50% of women were classified as 'high-risk' by the end of their pregnancy (Cheyne et al 2013), the specificity of such tools can be questioned. Cheyne et al's (2013) findings in fact echo our own, since half the FMU cohort did not give birth there, presumably because of the presence of one or more risk factors which made them ineligible for birth in the FMU.

The correlation between smoking and increasing levels of deprivation is well known (ISD 2013), as is smoking's association with the risk of preterm birth (Bernstein et al 2005). To our surprise we found that the proportion of women smoking at booking and during pregnancy was reportedly higher in the FMU cohort. This may indicate that the two cohorts were not as diverse as their SIMD-derived deprivation status may indicate. It is also possible that the smoking rates for the OU cohort were an under-estimate, but as all the data were obtained from the Information and Statistics Division (ISD) of the NHS in Scotland, this is only conjecture.

While several robust evaluations of midwife-led care have demonstrated significant benefits (Sandall et al 2010, 2013; Sutcliffe et al 2012), these have focussed principally on intrapartum care. Many analyses of MLU outcomes do not allow for an evaluation of antenatal care across all risk levels, even when analysing by 'intention-to-treat', because women must be considered low-risk at some stage (even if that risk status is revised).



Choosing to focus only on a FMU such as the one in this study largely avoids this difficulty because higher risk women can experience the care model, even if most of their antenatal care is scheduled for the OU.

Evaluations of the FMU in question have identified significant user input and a drive for normal birth as key components of the model (Winters and Nicoll 2006). In addition, a focus on individuals and their families, and open and balanced antenatal education are stressed (Leatherbarrow et al 2004). Flexible access to a small team of midwifery staff and an interactive online presence allow for genuine engagement with service users. Dealing with 'small niggly queries' in between scheduled visits is a posited benefit which encourages a sense of wellbeing and control and also leaves more time to deal with issues of greater concern during planned antenatal visits. The shared philosophy in the midwifery team promotes continuity of care, and in turn the women feel safe, secure and supported. These elements reflect some of the claimed benefits of the independent midwifery and Centering Pregnancy<sup>TM</sup> models (Milan 2005; Klima et al 2009). We are of course not saying that the OU care model does not attempt to provide flexible, women-centred, family-focused care with an open and balanced approach to antenatal education, but it is apparent that care models based within obstetric units are subject to organisational pressures (such as higher service user numbers and poorer staffing ratios) that do not always allow such aspirations to be realised - indeed, they may actually inhibit this (Walsh 2007). Any future work comparing models would need to assess this feature of the care package experienced by women.

This need for sensitive tailored maternity care is stressed in the Refreshed Framework for Maternity Services in Scotland as a means of reducing healthcare inequalities (MSAG 2011). Because of geographic and demographic factors there is an eclectic mix of models in Scotland, including various 'non-standard' models (BirthChoice UK nd; Tucker et al 2010),

making comparisons problematic. For our purposes we have used a particular FMU which has been well evaluated, not least for its focus on user involvement (Winters 2007).

We have to acknowledge that many factors can account for different preterm birth rates. We accounted for one such factor - the known difference between the two cohorts' socio-economic composition - by using multivariate regression, and found that the difference in preterm birth rates was still statistically significant. Since the odds ratios are adjusted for differences in other independent variables, any significant difference is noteworthy. While we acknowledge that the large sample sizes may have contributed to the likelihood of achieving a level of statistical significance, the fairly narrow confidence intervals for the adjusted odds ratios do indicate that a certain reliance can be made on these findings. However, and as we note elsewhere, this study is hardly conclusive, and we will need to conduct further work to explore this phenomenon. The lack of an overall statistically significant effect for deprivation at the 5% level does not obscure the likelihood of an effect from this variable, as is well evidenced elsewhere (Goldenberg et al 2008). Nevertheless, deprivation level does not explain all the difference in preterm birth rates between the two cohorts receiving different models of antenatal care.

The secondary outcomes are all likely to be heavily influenced by the place of birth. In fact, the numbers within the FMU cohort giving birth in the FMU and OU were almost identical, but the analysis was by where the women resided, and therefore what kind of antenatal care model they had received. Nevertheless, it is not surprising to find more favourable clinical outcomes such as higher normal birth rates and lower intrapartum analgesia usage in the FMU cohort. A future phase in our research is a matched prospective cohort analysis which will allow us to explore with greater confidence whether these outcomes appear to be significantly related to the antenatal care model. In that study we will need to provide a clear description of how care is offered and experienced in the respective environments.

In the event that the care model is shown to be beneficial, work will still be required to establish which features of the care model may be contributing to this difference. Causal mechanisms are difficult to prove even when known associations exist – such as smoking, which is a known confounding factor (Baba et al 2012; Källén et al 2013). We were surprised to find a higher reported rate of smoking in the FMU cohort given the generally accepted correlation between smoking and deprivation level (ISD 2013). No model, however well evaluated, will provide all the answers. Nevertheless, it is plausible that a model of care which is perceived to be less stressful, or which encourages a greater sense of control or wellbeing, may help to protect against this particular clinical outcome (Ruiz et al 2002; Rising et al 2004; Glynn et al 2008). Walsh (2000, 2007) claims that birth centres (an umbrella term that encompasses FMUs) can empower women, the inference being that there is something in the standard hospital-based package which does not facilitate this. Over three decades ago Rice and Carty (1977) noted that some women will opt for non-OU birth in an attempt to avoid the perceived constraints of hospital rules and regulations.

Around the world there are many different midwifery models of care (Davis-Floyd et al 2009), and these reflect local circumstances. In trying to maximise good outcomes we inevitably work with what is feasible. As explained earlier, while there have been encouraging evaluations of independent midwifery (Symon et al 2009) and Centering Pregnancy<sup>TM</sup> (Klima et al 2009; Dellos and Marshall 2011), the numbers engaged in such schemes in the UK have not to date allowed for large-scale quantitative analysis of the potential beneficial effects of a certain type of antenatal care. That some MLU evaluations tend to focus only on ‘low-risk’ women is also a limiting factor, but the FMU ‘broad risk’ model in the UK offers an opportunity to compare women of varied risk levels, and irrespective of eventual place of birth. Our data suggest that twice as many women experienced the FMU model of antenatal care as gave birth in that unit; nevertheless, they

appeared to benefit from the antenatal model of care, even if they did not give birth in the low risk unit. We have noted above the eclectic nature of FMUs, and this is a detail we will need to explore and explain in order to include other FMUs. If we can construct a typology of 'broad-risk' FMUs, we can incorporate other units in a much larger prospective matched cohort study with sufficient power to identify a significant difference in preterm birth rates.

### *Limitations*

An observational study such as this cannot fully take into account the many known confounding variables associated with preterm birth, but because of considerations of choice and the way clinical risk levels tend to be viewed, there are practical and ethical reasons why an RCT in this area would be challenging. We only examined data from one FMU, and to date there is no mechanism (other than a detailed survey of units) which would tell us how typical or atypical this unit is. The same consideration applies to the OU in this study. We therefore make no claims regarding generalisability of our findings. While we took socio-economic status into account and used regression to adjust for other variables, we concede the inherent selection bias in a study of this kind; there may be other factors which account for the different outcomes we identified. We have to proceed carefully if we are to identify those features of an antenatal care package which may be beneficial in terms of this particular outcome. While the eclectic nature of maternity units in the UK may make a multi-site study challenging, it is important to establish a sound evidence base if policy and practice are to be changed.

In an unfunded exploratory study such as this we were limited in terms of how many variables we could include. The limited ethnic diversity in the locations included in this study meant that we were not able to draw any conclusions about this variable. We have noted above the complexities involved in trying to accommodate estimates of risk levels.

*Conclusion*

This preliminary study has identified an apparently significant trend in preterm birth rates associated with a 'non-standard' model of antenatal care. We concede that this is an observational study, and we were not able to account for several possibly confounding variables. While both cohorts were 'mixed risk', we were not able to assess risk on an individual basis and therefore cannot exclude the possibility that differing risk levels between the cohorts may have accounted for the identified differences. Nevertheless, our findings resonate with other evaluations of 'non-standard' models of maternity care provision. The next step is to clarify what the salient elements are in these 'non-standard' models and identify how they can be measured. This may include assessing women's sense of control or wellbeing, or perceived stress levels. Thereafter we plan to establish a matched cohort analysis which can examine for differences in clinical outcome between different antenatal care models, while taking account of as many of the known variables as possible.

The multiplicity of factors associated with preterm birth means that tackling it will require many different strategies. If re-focussing midwifery models of care is potentially one of those strategies, then there is an ethical imperative to pursue this line of enquiry.

This study was unfunded.

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**Table 1 Comparison of socio-demographic characteristics and parity - FMU and OU care model cohorts**

	FMU (n=1,107)		OU (n=7,567)		Test statistic	p
	n	%	n	%		
<i>Deprivation quintile</i>						
SIMD1	105	9.6%	3660	48.4%		
SIMD2	346	31.6%	1289	17.0%		
SIMD3	356	32.5%	693	9.2%		
SIMD4	228	20.8%	977	12.9%		
SIMD5	60	5.5%	948	12.5%	$\chi^2_{\text{trend}}=151.79$ [df=1]	<0.001
<i>Parity</i>						
Primiparous	471	43.6%	3670	48.8%		
Para 1	384	35.6%	2392	31.8%		
Para 2+	225	20.8%	1465	19.5%	$\chi^2_{\text{trend}}=6.73$ [df=1]	0.010
<i>Smoking in pregnancy</i>						
Never	802	73.2%	5984	79.2%		
Current	246	22.5%	1180	15.6%		
Not known	47	4.3%	393	5.2%	$\chi^2=33.10$ [df=2]	<0.001
	Mean [range]	SD	Mean [range]	SD		
Age	31.36 [17-47]	6.00	30.75 [17-51]	6.08	t=5.20 [df=341] <sup>θ</sup>	0.002

Key:

OU – Obstetric Unit

FMU – Freestanding Midwifery Unit

SIMD - Scottish Index of Multiple Deprivation, where SIMD1 = most deprived

<sup>θ</sup> corrected for unequal variances

**Table 2** Comparison of gestation and birth weight - FMU and OU care model cohorts

	FMU (n=1,107)		OU (n=7,567)		Test statistic	p
	Mean [range]	SD	Mean [range]	SD		
Birth weight [g]	3417 [600-5320]	576	3353 [460-5660]	607	t=6.48 [df=316] <sup>θ</sup>	<0.001
Gestation	39.40 [23-42]	1.908	39.18 [22-43]	2.135	t=3.22 [df=8672]	0.001
<i>Gestational group</i>						
<28 weeks	3	0.3%	34	0.4%		
28-32 weeks	9	0.8%	98	1.3%		
33-36 weeks	45	4.1%	451	6.0%		
37-42 weeks	1050	94.9%	6977	92.2%		
43+ weeks	0	-	7	0.1%	$\chi^2_{\text{trend}}=7.69$ [df=1]	0.006

Key:

OU – Obstetric Unit

FMU – Freestanding Midwifery Unit

<sup>θ</sup> corrected for unequal variances

**Table 3**      **Place of birth by antenatal care model**

	FMU care model (n=1,107)		OU care model (n=7,567)	
Place of birth	n	%	n	%
OU	546	49.3%	7558	99.9%
FMU	549	49.6%	9	0.1%
Other OU	12	1.1%	0	-

Key:

OU – Obstetric Unit

FMU – Freestanding Midwifery Unit

**Table 4 Comparison of outcome measures for different antenatal care models: FMU vs. OU cohorts**

	FMU (n=1,107)		OU (n=7,567)					
	n	%	n	%	$\chi^2$	p	Adjusted OR for FMU cohort*	p
Preterm birth	57	5.1%	583	7.7%	9.23	0.002	0.73 [0.55-0.98]	0.034
Spontaneous labour onset	919	83.9%	5,643	74.6%	45.56	<0.001	1.74 [1.46-2.08]	<0.001
Analgesia: none / Entonox $\Omega$ only	588	53.7%	2601	34.4%	153.58	<0.001	2.17 [1.90-2.49]	<0.001
Spontaneous Vertex Delivery	788	71.9%	4803	63.5%	30.13	<0.001	1.46 [1.32-1.78]	<0.001
Low birth weight	54	4.9%	529	7.0%	6.46	0.011	0.79 [0.59-1.06]	0.118
Perinatal / Neonatal death	8	0.7%	71	0.9%	0.45	0.492	n/a	n/a

Key:

OU – Obstetric Unit

FMU – Freestanding Midwifery Unit

\* Adjusted for SIMD quintile, age, parity and smoking during pregnancy

$\Omega$  - Entonox: self-administered anaesthetic gas (50% oxygen; 50% nitrous oxide)

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